REMARKS

Claim 1 is amended. Support for the amendment to Claim 1 can be found in the specification, for example, at page 17, lines 15-34. No new matter is added by the amendment. Claims 1-12 are presently under examination.

Rejection under 35 U.S.C. § 103

Claims 1-12 are rejected under 35 U.S.C. § 103 Claims 1-12 as obvious over Lang, Keetch, Fulmer, Robinette, and Royston in view of Goto. Specifically, the Office Action states that it would have been obvious to combine the teachings of Lang of administering an irritant to prostate to develop a model of prostatitis with the teachings of Keetch, Fulmer and Robinette of administering other compositions to develop a model of prostatitis, with the teachings of Royston which teaches that HCl acts as a non-specific irritant and the teachings of Goto which teaches administration of HCl in developing a model of prostatitis.

Applicants respectfully traverse this rejection.

Applicants submit that the claimed nonbacterial prostatitis animal model is not obvious over the claimed references because no combination of these teaching would lead one to the presently claimed nonbacterial prostatitis model.

Claims

The presently claimed invention as amended above provides a nonbacterial prostatitis animal model exhibiting a prostate tissue damage characteristically observed in human chronic nonbacterial prostatitis and a lower urinary tract disorder characteristically observed in human chronic nonbacterial prostatitis, the animal model being a nonhuman animal, and being prepared by injecting hydrochloric acid beneath the prostatic capsule, wherein concentration of the hydrochloric acid ranges from 0.1N to 0.4N, wherein said animal model does not have tissue damage in urethral and bladder tissues.

The presently claimed invention provides a unique animal model having prostate tissue damage, and a pathology of lower urinary tract disorder, but not having tissue damage in urethral and bladder tissues.

In order to achieve the above remarkable result, it is important that the animal model is prepared by injecting hydrochloric acid beneath the prostatic capsule.

No Combination of the References Teach that Which is Claimed

No combination of the cited references would lead one of ordinary skill to develop an animal model having prostate tissue damage, and a pathology of lower urinary tract disorder, but not having tissue damage in urethral and bladder tissues.

The cited references of Lang et al., Keetch et al., Fulmer et al., Robinette, Royston D, and Goto do not teach model animals having prostate tissue damage, and a pathology of lower urinary tract disorder, but not having tissue damage in urethral and bladder tissues, because the injected substances or the injected parts are different.

Lang teaches use of ethanol and DNBS to develop an animal model of prostatitis. Lang teaches that 3 of 5 animals died before the seventh post treatment day. *Lang* at page 203, left column, top paragraph. Thus, it is clear that the animal model of Lang displayed substantial tissue damage, such as damage in urethral and bladder tissues, due to the location and/or contents injected into the mice. The teachings of Lang make clear that Lang did not prepare a nonbacterial prostatitis animal model similar to the claimed animal model being a nonhuman animal, which is prepared by injecting hydrochloric acid beneath the prostatic capsule, wherein concentration of the hydrochloric acid ranges from 0.1N to 0.4N. Applicants have developed a method for preparing nonbacterial prostatitis animal models by injecting hydrochloric acid beneath the prostatic capsule so as to result in an animal model of nonbacterial prostatitis that does not have tissue damage in urethral and bladder tissues. Thus, Applicants methods do not result in the severe, typically lethal, damage taught in Lang. As such, there are substantial differences between the teachings of Lang and the claimed animal model.

Lang cannot be combined with the other references to eliminate these substantial differences. These references do not provide any guidance to those of ordinary skill on how to modify the teachings of Lang so as to not exhibit the severe, typically lethal, amount of tissue damage incurred when practicing the method of Lang. Specifically, none of the references teaches or suggests injecting (a) hydrochloric acid (b) beneath the prostatic capsule. Lang teaches injection of ethanol and DNBS into the rat ventral prostate. While the Office Action points to Royston and Goto as teaching the use of hydrochloric acid, the Office Action appears to take the position that hydrochloric acid acts like any other irritant, and use of such would lead to identical results. As is clear from the contrast between the severe tissue damage and mortality taught by Lang in contrast to the animal model of Applicants' Examples, which does not have tissue damage in urethral and

bladder tissues, the results were not identical. There is no teaching in any of the references that by injecting (a) hydrochloric acid (b) beneath the prostatic capsule, a less damaged prostatitis animal model would result. One of ordinary skill looking to the additional cited references would not know how to modify the teachings of Lang in order to develop an animal model that does not have tissue damage in urethral and bladder tissues, the results were not identical. More particularly, nothing in any combination of these references would lead one of ordinary skill to believe that an animal prostatitis model possessing the claimed attributes could be developed by injecting (a) hydrochloric acid (b) beneath the prostatic capsule. Accordingly, Lang, alone or combined with the other cited references, does not render the claimed animal model obvious.

Goto's treatment of the vas deferens of animals with HCl does not lead to prostate tissue damage characteristically observed in human chronic nonbacterial prostatitis and a lower urinary tract disorder characteristically observed in human chronic nonbacterial prostatitis. The examples of Applicants' specification show that treatment of the vas deferens with HCl results in only slight development of prostatits. In particular, the specification, at page 39, lines 1-33 and Figures 1 and 2, teaches that treatment of the vas deferens with HCl results in temporary damage that is no longer present after 4 days, rendering this mode of administration unsuitable for developing a prostatitis model exhibiting prostate tissue damage characteristically observed in human chronic nonbacterial prostatitis and a lower urinary tract disorder characteristically observed in human chronic nonbacterial prostatitis. Therefore, one of ordinary skill, when performing Goto's HCl administration in the absence of bacteria, would realize that such administration would be unsuccessful in establishing an animal model of nonbacterial prostatitis.

There is no teaching in any other cited reference to remedy that which is lacking in Goto. Specifically, no reference would lead one of ordinary skill to inject hydrochloric acid beneath the prostatic capsule in order to develop a successful prostatitis model. The Examples of the present application make clear that the animal model claimed herein possesses clearly different characteristics from the animals of Goto's methods. No reference directs one of ordinary skill on how to change the site of injection in order to develop an animal model consistent with Applicants' claims. Goto itself teaches development of an animal model by including bacteria in the injection, not by changing the site of the injection. No combination of any of the references with Goto would lead one to inject hydrochloric acid beneath the prostatic capsule. As such, no combination of any of the references with Goto would lead to developing an animal model exhibiting a prostate tissue

damage characteristically observed in human chronic nonbacterial prostatitis and a lower urinary tract disorder characteristically observed in human chronic nonbacterial prostatitis.

Royston, in particular, provides nothing beyond the teachings of Goto. Royston teaches HCl-induced injury to rat lung. Nothing in Royston would lead one to expect that Goto's treatment of the vas deferens of animals with HCl would not lead to prostate tissue damage characteristically observed in human chronic nonbacterial prostatitis and a lower urinary tract disorder characteristically observed in human chronic nonbacterial prostatitis. Moreover, nothing in Royston would lead one to modify Goto to arrive at the claimed animal model. In particular, nothing in Royston would lead one to believe that injection of hydrochloric acid beneath the prostatic capsule would lead to developing a successful prostatitis model as is claimed herein, in order to overcome the shortcomings of Goto's treatment of the vas deferens of animals with HCl.

Fulmer, Robinette and Keetch all teach use of specifically active inflammation-inducing substances in generating prostatitis models. Nothing in any of these references suggests than anything other than very specific administrations and/or administration methods can be successful in generating a prostatitis model. Robinette and Keetch teach that not even minor variations of their methods can be made without destroying the reliability of the prostatitis model. Thus, nothing in these references would lead one to consider that Lang's or Goto's teachings could be modified by injecting hydrochloric acid beneath the prostatic capsule in order to develop a prostatitis model possessing all of the claimed characteristics. If anything, Fulmer, Robinette and Keetch are evidence that the results of even minor variations in methodology yield unpredictable variations in the resultant treated animal. As such, Fulmer, Robinette and Keetch serve as evidence that one of ordinary skill would have no expectation that injecting hydrochloric acid beneath the prostatic capsule would result in an animal model possessing all of the claimed characteristics. Accordingly, the teachings of Fulmer, Robinette and Keetch, alone or combined, cannot be combined with Lang or Goto or Royston in such a way as to render the claimed animal model obvious.

CONCLUSION

In view of the above, Applicants respectfully maintain that claims are patentable and request that they be passed to issue. Applicants invite the Examiner to call the undersigned if any remaining issues might be resolved by telephone.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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